

***United States Court of Appeals
for the Second Circuit***



**PETITIONER'S
REPLY BRIEF**

77-4097

ORIGINAL

To be argued by
MILTON A. BASS

In The

United States Court of Appeals

For The Second Circuit

THE NATIONAL NUTRITIONAL FOODS ASSOCIATION,
THE NATIONAL ASSOCIATION OF PHARMACEUTICAL
MANUFACTURERS AND SOLGAR CO., INC., et al.,

Petitioners,

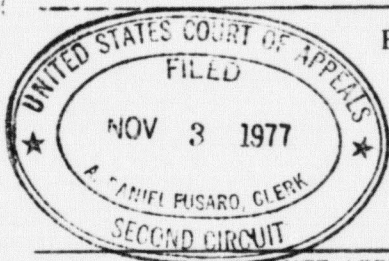
vs.

DONALD KENNEDY, Commissioner of Food and Drugs, and
UNITED STATES DEPARTMENT OF HEALTH
EDUCATION & WELFARE, Food and Drug Administration,

Respondents.

*On Petition to Review Orders of the Food and Drug
Administration, United States Department of Health, Education
and Welfare.*

**REPLY BRIEF FOR PETITIONERS THE NATIONAL
NUTRITIONAL FOODS ASSOCIATION, THE NATIONAL
ASSOCIATION OF PHARMACEUTICAL
MANUFACTURERS AND SOLGAR CO., INC.**



BASS, ULLMAN & LUSTIGMAN

Attorneys for Petitioners

NNFA, NAPM and Solgar

747 Third Avenue

New York, New York 10017

(212) 751-9494

(10127)

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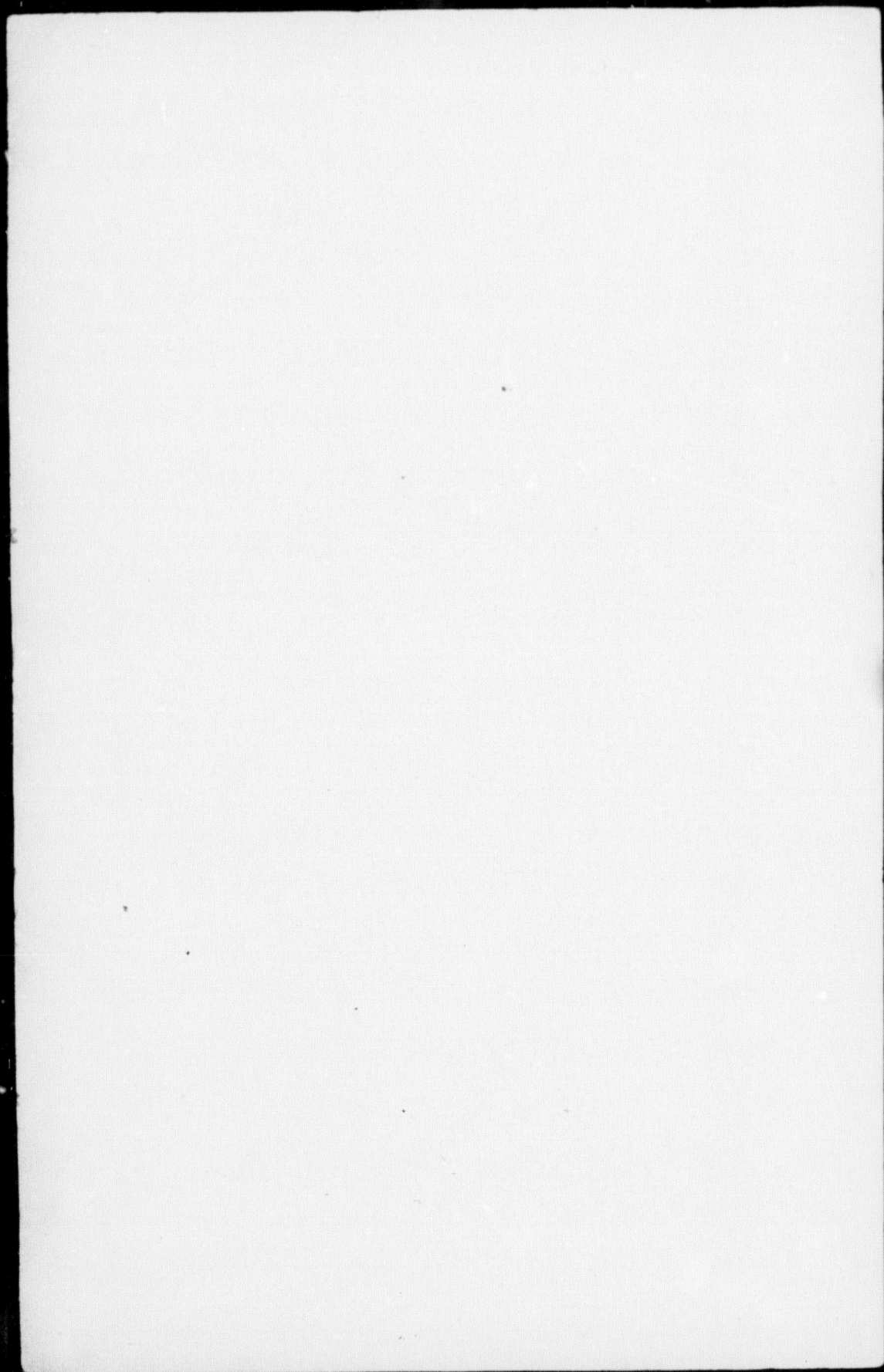


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In The
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THE NATIONAL NUTRITIONAL FOODS ASSOCIATION,
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*On Petition to Review Orders of the Food and Drug
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REPLY BRIEF FOR PETITIONERS
The National Nutritional Foods Association,
The National Association of Pharmaceutical
Manufacturers and Solgar Co., Inc.

Petitioners, National Nutritional Foods Association (NNFA), National Association of Pharmaceutical Manufacturers (NAPM) and Solgar Co., Inc., respectfully submit this reply to the respondents' brief. Respondents' answer to petitioners' ten issues begins on page 27 of their brief.

ARGUMENT

I.

RESPONDENTS' FAILURE TO FOLLOW STATUTORY PROCEDURAL REQUIREMENTS.

Respondents have failed to comply with the requirements of 5 U.S.C. §553 in promulgating the instant regulations as final rules in spite of the fact that Congress expressly directed that they do so (Public Law 94-278).¹ Because of the failure of the respondents to comply with the applicable statutory procedural requirements, we do not have a record or factual basis for the regulations, nor can we determine whether there is substantial evidence to support the regulations, as required by the Statute.

Contrary to respondents' contention, the issue before us is not whether respondents desired to design a new scheme for the regulation of vitamin and mineral supplements, but, rather, that Congress mandated substantial changes in the agency's regulations. Congress struck down the basic structure of the prior regulations by prohibiting the agency from establishing limitations on potencies of vitamins and minerals and limitations on combinations of vitamins, minerals and food ingredients. These new statutory provisions effectively destroyed the Standards of Identity which the agency had established.

The respondents have failed to address the legal questions relevant to any possible exemption under 5 U.S.C. §553

1. "(b) The Secretary of Health, Education, and Welfare shall amend any regulation promulgated under the Federal Food, Drug, and Cosmetic Act which is inconsistent with section 411 of such Act (as added by subsection (a)) and such amendments shall be promulgated in accordance with section 553 of title 5, United States Code." 21 U.S.C. §350.

although these exemptions have been discussed in detail, in petitioners' original brief. Respondents argue that there was no need for the agency to give further opportunity for comment, as required by the Statute, but fail to set forth any basis or support for this alleged lack of need within the statutory exemption.

On page 29 of their brief, respondents state that it was their understanding that Public Law 94-278 preempted §701(e) of the Statute. Although respondents' understanding is incorrect, it is significant to note that the respondents even failed to comply with the notice and comment procedure of §553. Contrary to respondents' understanding, §553(b) clearly recognizes the requirement to adhere to statutory procedures, and Congress in Public Law 94-278 expressly states that the respondents shall comply with §553 in amending their regulations to comply with the new statutory amendments. We therefore do not have any statutory construction issue in the instant proceeding.

Respondents state, on page 30 of their brief, that it never occurred to the Commissioner that anybody would question the agency's compliance with a direct mandate of the Congress. We agree. Congress did give the respondents a direct mandate to comply with §553 of Title 5 of the U.S. Code. It is conceivable that if Congress had not repeated the statutory direction for procedural requirements, the respondents might be arguing to this Court that the silence of Congress indicates that it did not have to comply with §553 and that the new regulations were simple obedience to the new Statute. In essence, respondents have failed to address the legal questions involved in their assertion that notice and public comment are impracticable, unnecessary or contrary to public interest. They repeat the words of the Statute without demonstrating any facts which would bring this proceeding within those statutory exemptions, as set forth in the legislative history and relevant cases which interpret and construe these statutory provisions (Petitioners' Brief, pp. 10-18).

II.

**THE AGENCY IMPROPERLY PROMULGATED A
STANDARD OF IDENTITY FOR DIETARY
SUPPLEMENTS INTENDED FOR USE BY PREGNANT
AND LACTATING WOMEN, AND CHILDREN UNDER
THE AGE OF 12 YEARS.**

Respondents argue that Congress prohibited them from creating a Standard of Identity for adults, but left open the power to create Standards of Identity for pregnant or lactating women or children. Thus, they state that they have every right to continue the old Standard of Identity, based upon the old record, for these limited groups. The old Standard of Identity was allegedly based upon the contention that it was necessary to create a standard to avoid public confusion. The extensive record in the prior proceeding involved evidence and legal arguments directed to that issue.

The issue here presented, however, is whether the standard that the agency has now issued is supported by the prior record. When Congress struck down the power of the respondents to create a Standard of Identity for adults, it left open the possibility of a standard for limited groups because of "unrecognized" or "unanticipated" harm. This fact is conceded by respondents on page 32 of their brief where they cite the Conference Report, which explains the reasons for this exception in the Statute. In this regard, Senator Proxmire clearly stated that this reservation does not mean that the Food and Drug Administration can once again arbitrarily set limits or create a standard for otherwise safe vitamin or mineral products. The respondents have failed to set forth any objective standard within these parameters.

The old basis of public confusion is clearly not applicable. The prior record does not include any issue involving the new requirements laid down by Congress and ostensibly used by

respondents. There is no evidence before this Court which demonstrates that the ingredients and potencies used in the standards for these limited groups is based upon safety factors. The RDA's employed by respondents do not involve safety determinations and do not even include a category for children 4 to 12 years of age, which is the standard established by respondents.

Contrary to respondents' statement on page 32 of their brief, petitioners do submit that the new Standard of Identity is illogical. It prevents a pregnant woman from buying a dietary supplement with rutin whereas that same woman can buy a dietary supplement with rutin if she is not pregnant. Respondents' ruling would be logical if they can demonstrate that it would be unsafe for a woman to use a dietary supplement containing rutin when she is pregnant. Respondents have failed to submit such evidence. Rutin is only one example of many ingredients which are banned from the new standard, as well as limitations on potency, which are contained in this new standard, unrelated to any question of safety.

Congress has clearly set forth its policy determination that the agency cannot limit potencies and combinations or create Standards of Identity for adults, as the respondents attempted to do in the prior regulations. In the instant proceeding, respondents have created a Standard of Identity for a limited group without any factual basis whatsoever.

III.

THE AGENCY HAS IMPROPERLY MAINTAINED MINIMUM POTENCY REQUIREMENTS FOR DIETARY SUPPLEMENTS.

Under the original regulations, the agency created a regulatory structure whereby a dietary supplement had to conform to a Standard of Identity in which each ingredient

contained 50% to 150% of the U.S. RDA. The agency's original premise was that it had a right to create a Standard of Identity for dietary supplements and thus had a right to set the quantities for the ingredients in the standard. The new regulation is based upon an entirely different premise. The respondents now contend that anything less than 50% of the RDA's is insignificant or useless. Once again the importance of following the statutory procedural requirements is evident. We are here presented with a new issue which was not adjudicated in the prior proceeding.

Petitioners submit that quantities less than 50% of the RDA's in a dietary supplement are significant and in fact even preferred by many nutritionists. The purpose of a dietary supplement is not to substitute for all food intake, but rather to supplement the daily diet.

It is significant that in another regulation the agency appears to agree with petitioners where it provides that no claim can be made that a food is a significant source of a nutrient unless it contains at least 10% of the RDA's.² If the respondents now wish to pursue their allegation that a nutrient in a dietary supplement is worthless unless it contains at least 50% of the U.S. RDA's, then this issue should be presented for comment and relevant evidence.

Contrary to respondents' statement on page 34 of their brief, this Court did not hold that there was nothing arbitrary in drawing a line at 50%, as a minimum potency requirement relative to an issue of whether such a potency would be useless or insignificant. Rather, this Court merely considered whether 50% was arbitrary for the purpose of drawing a line in creating a Standard of Identity under §401 of the Statute. The present regulation has nothing to do with the Standard of Identity.

2. 21 C.F.R. §101.9(c)(7)(v).

As set forth in petitioners' original brief, the respondents' position is arbitrary and irrational when viewed against the congressional enactment which permits the inclusion of vitamins, minerals and other ingredients which the FDA considers to be totally worthless and without significance in human nutrition.

We agree that the public should be protected, but respondents fail to demonstrate that anything less than 50% of the RDA would be useless or insignificant for dietary supplement purposes.

IV.

THE AGENCY ERRED IN CONTINUING LIMITATIONS ON THE MAXIMUM QUANTITIES OF COMPONENT OF DIETARY SUPPLEMENTS.

Respondents argue that this provision is carried over verbatim from the old regulations. Petitioners agree, and that is precisely what is wrong with this regulation. The Statute passed by Congress renders this regulation improper in its present form. The original regulation, which limited the quantities of components of dietary supplements, was premised upon the creation of Standards of Identity under §401 of the Statute. Congress has ruled that the agency cannot create such a Standard of Identity. Thus, it is improper and inappropriate for the agency to attempt to establish a regulation which would limit the maximum quantity of an ingredient to the amount needed for a physical or technical effect. On the contrary, Congress has expressly ruled that an ingredient can be used in a product even if the FDA claims that the ingredient has no use or effect whatsoever.

On page 35 of their brief, the respondents argue that the purpose of this provision is to assure the safety and effectiveness of the dietary supplement. Unfortunately, that is not what the

regulation provides. If the limitations on maximum quantities were directed solely to questions of safety, we would not be arguing this issue before this Court. On the contrary, there would then be no need for such a regulation. The statute, Section 402, already renders a product adulterated and banned from sale if it is unsafe.

The regulation provides that the dietary supplement may not have a component which exceeds the amount reasonably required to accomplish its intended physical or technical effect. This provision has nothing to do with safety and would be applicable to ingredients in a product which can be designated as a base, a vehicle or a flavor. It is significant that the respondents do not address the real question presented by the regulation.

Petitioners submit that the attempt to retain this regulation is contrary to and inconsistent with the statutory amendments which Congress enacted to prohibit the imposition of the old vitamin regulations. The only basis which Congress left open for limiting the quantity of these substances is the question of safety.

It may be noted that the reference to this Court's earlier ruling affirming such limitations was not premised upon a question of safety, but rather the right to impose such limitations as part of the creation of a Standard of Identity. As heretofore noted, the concept underlying the creation of a Standard of Identity is that there is a need to prevent confusion. This provision would be consistent with the creation of a Standard of Identity, but is without statutory support and in fact inconsistent with the new statutory amendments.

**THE NOMENCLATURE REQUIRED BY THE
REGULATIONS IS ARBITRARY, CAPRICIOUS AND NOT
IN ACCORDANCE WITH LAW.**

Respondents argue that this provision was in the original regulations and was originally sustained by this Court. That is correct. Respondents, however, do not add that Congress has set aside the agency's power to create such a Standard of Identity. The nomenclature issue was originally premised upon its use in designating a Standard of Identity and obviously it was proper to have a specific name adopted to identify a Standard of Identity.

The respondents further argue that the Commissioner concluded that it was necessary to use this nomenclature to prevent consumer confusion. Respondents are correct. The premise for a Standard of Identity was based upon the agency's contention that it was necessary to prevent consumer confusion. Congress, however, has ruled otherwise.

We are now considering a new issue. We are no longer considering a term which would be used to identify a Standard of Identity, but rather appropriate language to describe a product. This issue must be considered *de novo*, including all possibilities of label disclosure so as to properly identify a product for the consumer. In this regard, the agency has not responded to petitioners' argument with respect to folic acid, as set forth in pages 28 and 29 of their original brief.

Petitioners respectfully submit that the respondents are attempting to retain a provision of the old regulations separate and apart from the context in which it was originally created and separate and apart from its original purpose.

VI.

**THE AGENCY ERRED IN FAILING TO MODIFY THE
DIETARY SUPPLEMENT REGULATIONS TO TAKE INTO
ACCOUNT THE STATUTORY DEFINITION OF THE
TERM FOOD FOR SPECIAL DIETARY USE.**

**A. The Regulations Improperly Prohibit "Dietary" Claims for
Non-Vitamin And Mineral Food Ingredients.**

On page 38 of their brief, respondents argue that the effect of the new Statute is to preclude the listing of any ingredients that are not vitamins or minerals on the principal display panel. Petitioners respectfully disagree. That is not what the Statute states and that is not what was intended. Significantly, the implication respondents attempt to create by this statement is negated by the fact that the new Statute affirmatively permits the advertising of the product to include those very same ingredients which are not vitamins or minerals.

The new Statute makes the proposed regulation improper in that the Statute recognizes and includes so-called non-essential food ingredients as foods for special dietary use and dietary supplement products. It was the decision of Congress that food ingredients can properly be sold as dietary supplements and that they properly come within the statutory definition of foods for dietary use irrespective of the fact that the FDA has ruled that such ingredients are not recognized as essential in human nutrition.

Petitioners respectfully submit that respondents are in error in failing to distinguish between accepted nutritional property and dietary property in the new statutory definition.

B. The Agency Has Improperly Retained The Prohibition Against Any Representations That A Vitamin Or Mineral Is Effective In The Prevention of Disease.

With respect to the attempt of the respondents to prohibit truthful representations that a vitamin or mineral is effective in the prevention of a disease, it is significant that the respondents have heretofore argued before this Court that the prophylactic use of a vitamin is a food use rather than a drug use. *NNFA v. Mathews*, 557 F.2d 325 (2d Cir. 1977).

In *NNFA v. Mathews*, *supra*, Commissioner Schmidt of the Food and Drug Administration, submitted an affidavit with the following statement:

"Unlike most articles recognized in the U.S. Pharmacopeia and the National Formulary, which are included because of therapeutic usage, vitamins A and D are specifically recognized in the U.S.P. and N.F. for prophylactic (food) usage. In my judgment, while the Act provides that an article is deemed to be a drug if 'recognized' in the U.S.P. or N.F., *a vitamin preparation should nevertheless not be classified as a drug on this basis with respect to a usage which is specifically recognized by these compendia to be a prophylactic (food) usage.*" (emphasis added) (Schmidt Affidavit, Feb. 13, 1975, pp. 6-7).

The respondents' argument in this case is not a logical one in view of the fact that, by definition, an essential nutrient prevents illness caused by a deficiency of that nutrient.

Petitioners respectfully submit that, contrary to respondents' statement on page 40 of their brief, the recent

Supreme Court decisions on the right of commercial speech are relevant to the instant regulation which prohibits the communication of truthful information. An example of the kind of information which would be prohibited under this regulation is the discussion of Vitamin C which is set forth on the package of "cheerios" breakfast cereal (see addendum, *infra*).

VII.

THE AGENCY ERRED IN FAILING TO MODIFY THE PROVISIONS OF THE DIETARY SUPPLEMENT REGULATIONS RELATING TO THE LISTING OF INGREDIENTS ON THE LABEL OF DIETARY SUPPLEMENTS.

The separate listing requirement in the new regulation is not mandated by and is in fact inconsistent with the new statutory amendments. Reference is respectfully made to the argument on pages 34 to 37 of petitioners' original brief, which respondents have failed to address.

Respondents' reference to the fact that there is a right to petition for exemptions does not respond to the issue. We are not discussing an exemption to a proper regulation, but rather the basic compliance required under the new statutory amendments.

VIII.

THE AGENCY ERRED IN THE CONDUCT OF THE REMAND DIRECTED BY THIS COURT.

A. The Promulgated Standard of Identity Fails to Make Provision For Many Essential Nutrients.

The respondents have failed to make any response to petitioners' contention that the agency has not complied with the

clear directive of this Court in promulgating the new Standard of Identity. *NNFA v. FDA*, 504 F.2d 786-787 (2d Cir. 1974). (See Petitioners' Brief, pp. 37-39.)

B. The Agency Failed To Comply With This Court's Direction As To The Criteria For Future Modification Of The Standard Of Identity.

Respondents have failed to address the issue, raised by petitioners, that the agency has not complied with this Court's directive to apply the seven specific criteria for the establishment of a Standard of Identity. *NNFA v. FDA*, *supra*, 504 F.2d at 785. (See Petitioners' Brief, pp. 39-41).

C. The Final Regulations Improperly Restrict Representations Concerning The Availability Of Iron In The Food Supply For The Purpose Of Meeting The Requirements Of Children And Women Of Child-Bearing Age.

Petitioners respectfully submit that the respondents have not complied with this Court's directive to insert a proper qualification in §125.2(b)(2), *NNFA v. FDA*, *supra*, 504 F.2d at 802. This Court was discussing the ability to obtain an adequate supply of iron from a *balanced diet*, rather than the new language now used by the agency of a *diet of conventional foods*. The agency has effectively altered the limitation which was previously upheld by this Court. Reference is respectfully made to pages 41 and 42 of petitioners' original brief.

D. The Agency Erred In Refusing To Modify §105.60(b)(2) As Regards Vitamin B-6 (Pyridoxine), Folic Acid And Magnesium.

It appears that the respondents are attempting to shift the statutory burden of proof from the agency to the petitioners. Under the Statute, it is required that the Commissioner's findings must be supported by substantial evidence (§701(f) of the Statute). The present record contains uncontradicted evidence

supporting petitioners' contention, as set forth on pages 42 and 43 of petitioners' original brief, that §105.60(b)(2) of the regulations does not properly apply to Vitamim B-6, folic acid and magnesium.

Petitioners submit that the rule of law is not that the Commissioner's conclusion should not be altered "unless it is clearly wrong" (Respondents' Brief, p. 43), but rather that the conclusion of the Commissioner must be supported by substantial evidence.

E. The Regulations Improperly Prohibit Representations That There May Be A Difference Between Natural And Synthetic Vitamins.

The issue before us is not whether there is a procedure where injustices may be corrected by future applications. On the contrary, in the instant case, petitioners are referring to a finding which was officially made by the Commissioner that there is a difference between natural and synthetic Vitamin K (40 F.R. p. 23248, May 28, 1975). It is inconceivable that the respondents now desire petitioners to apply to the Commissioner to make such a finding.

IX.

THE AGENCY IMPROPERLY INCORPORATED FOOD ADDITIVE RESTRICTIONS ON VITAMINS AND MINERALS AS PART OF THE DIETARY SUPPLEMENT REGULATIONS.

The classification of vitamins and minerals as food additives, under the statutory definition, was never raised as an issue in this proceeding, was never tried and was never ruled upon. Respondents are attempting to incorporate a ruling on this question after the remand from this Court. This Court did not include that issue in its remand.

The Conference Report referred to by respondents, on pages 44 and 45 of their brief, does not state that vitamins and minerals are food additives under the Statute, but rather state that a vitamin, mineral or other food ingredient would be subject to the food additive section if it meets the criteria of the definition of a food additive under §201(s) of the Act [21 U.S.C. §321(s)].

X.

THE REGULATORY PROVISIONS CONCERNING EXPIRATION DATING FOR DIETARY SUPPLEMENTS ARE INVALID.

Respondents do not address the issue raised by petitioners. Petitioners do not object to the establishment of an expiration date of these products. Petitioners do object to the fact that the agency is applying a 100% potency requirement for the expiration date. This requirement is inconsistent with the standard laid down by the United States Pharmacopeia (U.S.P.) and is contrary to manufacturing realities. The U.S.P. is an official compendium recognized as such by the United States Government and specifically in the Federal Food, Drug, and Cosmetic Act. The U.S.P. has established tolerances for vitamins, minerals and pharmaceutical products. Thus, with respect to Vitamin C tablets, for example, the U.S.P. provides that the tablet shall contain not less than 90% and not more than 110% of the labeled amount.

Petitioners respectfully submit that the regulation should be changed to reflect the official tolerance standards established by the United States Pharmacopeia.

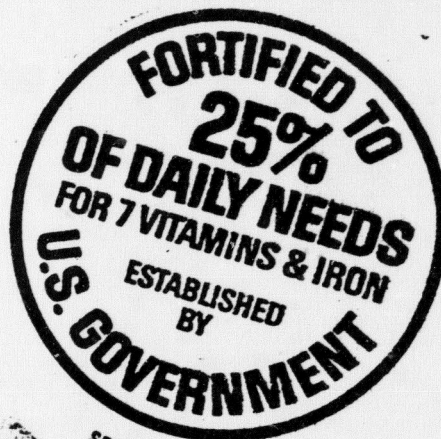
CONCLUSION

For the foregoing reasons and those set forth in petitioners' principal brief, petitioners respectfully submit that these regulations should be vacated.

Respectfully submitted,

BASS, ULLMAN &
LUSTIGMAN
Attorneys for Petitioners

General  Mills



SEE SIDE PANEL

Cheerios®

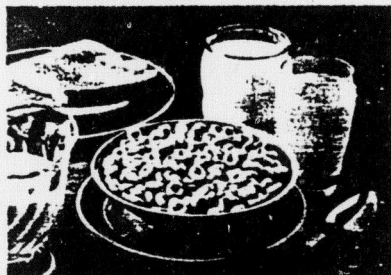
**TOASTED OAT CEREAL
MADE FROM THE GRAIN HIGHEST IN PROTEIN**

VITAMIN C

Vitamin C has several important functions in the body, such as helping to form bones and teeth and to develop connective tissues. Vitamin C also plays a significant role in wound healing and maintaining strong blood vessels.

A deficiency of vitamin C is called scurvy, which is relatively uncommon in the United States today. However, hundreds of years ago, sailors on long ocean voyages frequently suffered from scurvy. Late in the 18th century, it was discovered that when British sailors consumed lemons and limes (which are high in vitamin C) throughout their long sea voyages, they did not suffer from scurvy. Since this time, the British sailor has been known as a "limey".

Dietary sources of vitamin C include citrus fruits, strawberries, tomatoes and potatoes.



This Cheerios breakfast provides a variety of nutrients, including protein, fat, carbohydrate, vitamins and minerals. Cheerios is a very important part of this nutritious breakfast because a one ounce serving of Cheerios supplies 25% of the U.S. Recommended Daily Allowances of seven important vitamins and iron.

ADDENDUM

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National Nutritional foods Associateon
NATIONAL NUTRITIONAL FOODS ASSOCIATION,
NATIONAL ASSOCIATION OF PHARMACEUTICAL
MANUFACTURERES & SOLGAR CO, INC.,

Petitioners

- against -

Affidavit of Service by Mail

DONALD KENNEDY, Commissioner of Food & Drugs
UNITED STATES DEPT OF HEALTH EDUCATION
& WELFARE, Food & Drug Adm.
Respondents.

TE OF NEW YORK, COUNTY OF NEW YORK ss.:

I, Robert L. Martinez, being duly sworn, depose and say that deponent is not a party to the
1, is over 18 years of age and resides at 1165 Morris Avenue; Bronx, New York; 10456
on the 3rd day of November, 1977, deponent served the annexed

ly Brief

upon

1. Miles Robinson

attorney(s) for

2. Charles R. McConachie

in this action, at 1. 10120 Chapel Road; Potoma, Maryland
2. U.S. Dept. of Justice; Washington, D.C.

the address designated by said attorney(s) for that
ose by depositing a true copy of same, enclosed in a postpaid properly addressed wrapper in a
Office Official Depository under the exclusive care and custody of the United States Post Office
artment, within the State of New York.

rn to before me, this 3rd
of November, 19 77

Robert L. Martinez

ROBERT T. BRIN
OTARY PUBLIC, State of New York
No. 31-0418950
Qualified in New York County
mission Expires March 30, 1979